UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	MDL No. 1:13-MD-2428-DPW
	REDACTED FILING
This Document Relates to:	
Charles Cameron, Individually and as Wrongful Death Beneficiary of Charles Cameron, Sr., Case No. 1:13-cv-12446-DPW;	
Daniel Carter, Individually and on Behalf of the Wrongful Death Beneficiaries of Anniece Carter, Case No. 1:13-cv-12459-DPW;	
Geraldine Dillingham, as Next of Kin and Personal Representative of Estate of Ronnie Dillingham, Case No. 1:15-cv-12796-DPW;	
Alex Kazos, as Next of Kin and Personal Representative of Estate of Nick Kazos, Case No. 1:15-cv-12376-DPW;	
Kathleen Palmaccio, as Next of Kin and Personal Representative of Estate of John Palmaccio, Case No. 1:15-cv-12474-DPW;	
Sharon Randall, as Next of Kin and Personal Representative of Estate of Winfitch Randall, Case No. 1:15-cv-12735-DPW;	
Amy Riben, Wife, and Max Riben, Husband, And Their Marital Community, Case No. 1:15-cv-11134-DPW;	
Tamika Smith, as Next of Kin and Personal Representative of Estate of Cynthia Reed, Case No. 1:15-cv-12768-DPW;	
Sophia Walker, Individually and on Behalf of the Wrongful Death Beneficiaries of Hattie Myles, Case No. 1:13-cv-12487-DPW;	

Angelos Zachery, et al., Individually and as Executor of the Estate of Nellie Fredrick McClendon,	)
Case No. 1:14-cv-13150-DPW	)

MEMORANDUM IN SUPPORT OF FMCNA'S MOTION FOR SUMMARY JUDGMENT ON THE CLAIMS OF OPT-OUT PLAINTIFFS INVOLVING NATURALYTE

Pursuant to Federal Rule of Civil Procedure 56, Defendants, Fresenius Medical Care Holdings, Inc., Fresenius USA, Inc., Fresenius USA Manufacturing, Inc., and Fresenius USA Marketing, Inc. (collectively "FMCNA") submit this memorandum in support of their motion for summary judgment on the claims of all opt-out plaintiffs who lack evidence that the acid concentrate used in the last dialysis treatment prior to the alleged injury was GranuFlo®, rather than NaturaLyte®. This motion applies to 10 out of the 20 cases on the current opt-out list. As set forth in its pleading filed on June 19, 2017 (Doc. 1893), FMCNA has identified additional grounds for summary judgment in opt-out cases and intends to file additional motions for summary judgment, some of which will be directed to some of the same plaintiffs that are subject to this motion. FMCNA expects that all of the opt-out cases will be subject to one or more dispositive motions (a motion for summary judgment or motion to dismiss).

In the following opt-out cases, Plaintiffs' counsel asserts that NaturaLyte® was used in the patient's last dialysis treatment: Geraldine Dillingham (Ronnie Dillingham); Alex Kazos (Nick Kazos); Kathleen Palmaccio (John Palmaccio); Sharon Randall (Winfitch Randall); Tamika Smith (Cynthia Reed); and Max Riben (Amy Riben). In addition, FMCNA has identified two additional cases in which available records indicate NaturaLyte® was used: Daniel Carter (Anniece Carter) and Angelos Zachery (Nellie Fredrick McClendon). Further, FMCNA has identified two cases in which the records are insufficient to establish that the patient was dialyzed with GranuFlo®, rather than NaturaLyte®: Charles Cameron (Charles Cameron, Sr.); and Sophia Walker (Hattie Myles).

I. INTRODUCTION

The product that inspired this litigation is GranuFlo®, FMCNA's dry acid concentrate that contains sodium diacetate and contributes a total of 8 mEq/L of acetate to the dialysate

solution. Dr. Paul Miller, a Louisiana nephrologist who concedes that he has no issue with the 4 mEq/L of acetate in NaturaLyte®, has waged a personal campaign against FMCNA and GranuFlo® since 2012, including by instigating the labeling recall with the FDA and related false claims litigation in his home state. Copying his theory, Plaintiffs commenced these personal injury cases in this MDL based on allegations that GranuFlo® had more acetate than other acid concentrates, physicians did not understand how to use it, and this caused patients to experience elevated serum bicarbonate levels, which in turn triggered fatal cardiac arrests during dialysis. While this theory has proven dubious for GranuFlo®, it is patently inapplicable to NaturaLyte®, as underscored most recently by the defense verdict in the Dial case.

NaturaLyte® is a liquid acid concentrate that contains 4 mEq/L of acetate, half the amount in GranuFlo®. NaturaLyte® contains no sodium diacetate, and it has been in use **since 1981**. Competitive products contain the same amount of acetate as NaturaLyte® and disclose the acetate contents in the same way on their labels. Plaintiffs' original Master Complaint admitted that it is part of the "traditional" acid concentrates, see MDL Doc. 467-1, ¶¶ 1, 97, 107, and Plaintiffs' NaturaLyte® expert, Dr. Borkan, has testified that this same amount of acetate is "conventional," "default," "typical," "baseline," and "acceptable." Indeed, Dr. Borkan treats his own patients with NaturaLyte®. Other nephrology experts retained by Plaintiffs, likewise, have testified that they safely use dialysates containing 4 mEq/L of acetate in their own practices.

In sum, FMCNA seeks summary judgment because Plaintiffs have no evidence to support their theory that NaturaLyte® injured any patient in any opt-out case. A jury rejected the plaintiff's claims involving NaturaLyte® in the Dial trial, and there is no reason to believe the outcome would be any different in any of the opt-out cases involving that product. On the contrary, Plaintiffs' insistence on pressing forward with NaturaLyte® cases has proven

unfounded. Accordingly, summary judgment now should be entered in favor of FMCNA in any opt-out case where the plaintiff is unable to establish that the patient's last dialysis treatment prior to injury used GranuFlo®, rather than NaturaLyte®.

II. UNDISPUTED MATERIAL FACTS

A. NaturaLyte®

NaturaLyte® and GranuFlo® are both acid concentrates manufactured by FMCNA. NaturaLyte® is a liquid acid concentrate that contains various electrolytes and 4 milliequivalents per liter (mEq/L) of acetic acid. SOF ¶ 1; 2d Amended Master Complaint ¶ 97 (Doc. 1232). When combined with a bicarbonate concentrate and water, NaturaLyte® provides 4 mEq/L of acetate to the dialysis solution. Id. GranuFlo® is a dry powder acid concentrate that contains various electrolytes, 4 mEq/L of sodium acetate and 4 mEq/L of acetic acid (that together are present in the form of sodium diacetate). SOF ¶ 2; 2d Amended Master Complaint ¶ 98. When combined with a bicarbonate concentrate and water, GranuFlo® provides 8 mEq/L of acetate to the dialysis solution. Id.

The U.S. Food and Drug Administration cleared NaturaLyte® for marketing **in 1981**. SOF ¶ 3. FDA cleared NaturaLyte® pursuant to Section 510(k) of the Medical Device Amendments of 1976, which allows manufacturers to market products that are "substantially equivalent" to medical devices that were already on the market when the MDA took effect. SOF ¶ 5. In the years since NaturaLyte® was cleared for sale, every manufacturer of acid concentrates for hemodialysis has offered a liquid product with 4 mEq/L of acetate, and they continue to do so. SOF ¶ 6. As Plaintiffs' original Master Complaint acknowledged, "All acid concentrates (liquid or dry) contain acid," and "[l]iquid products" generally contain acid in the form of "acetate." SOF ¶ 13; Master Complaint ¶ 105 (Doc. 467-1).

B. Plaintiffs' Allegations and Expert Testimony

Plaintiffs' original theory of liability factually applied only to GranuFlo®. The Master Complaint identified the accused products as follows:

> 1. The products that are the subject of the litigation **are any dry acid concentrate**, whether it be labeled by the Defendants as "GranuFlo" or "NaturaLyte" or both, **yielding a concentration of acetate greater than 4 meq/L** when put into solution for use in dialysis, by including sodium diacetate in the product's formulation. These products are described hereafter collectively as "NaturaLyte and/or GranuFlo".

SOF ¶ 11; Doc. 467-1 at ¶ 1 (emphasis added). Plaintiffs made clear that their issue is with sodium diacetate – a dry form of the liquid acetic acid used in liquid acid concentrate products. They characterized liquid acid concentrates as "traditional" acid concentrate products. SOF ¶¶ 12, 14; Doc. 467-1 at ¶¶ 97, 107 (emphasis added). Indeed, it appears that the only reason Plaintiffs used the word "NaturaLyte" in the original Master Complaint is because, at one time, FMCNA's dry acid concentrate product was sold under the trade name "NaturaLyte GranuFlo." SOF ¶ 15; Ex. 9 (2003 GranuFlo® 510(k)).

Once FMCNA provided fact sheets for individual patients, Plaintiffs realized that thousands of the cases they had filed involved people who had never received GranuFlo® – FMCNA's lone sodium diacetate product – as part of their dialysis treatment. See SOF ¶¶ 16-17; Doc. 725, at p. 2; Doc. 1178, at p. 2. It turned out that in certain of the cases, including several of the opt-out cases remaining today, the patient was treated with NaturaLyte® liquid acid concentrate – a product that is not dry, does not contain sodium diacetate, and contributes only 4 mEq/L of acetate. Rather than dismissing these cases as inconsistent with their own theory, however, Plaintiffs filed an Amended Master Complaint that added NaturaLyte® liquid acid concentrate as an accused product. SOF ¶¶ 16, 18; Doc. 725-1 at ¶ 1; Doc. 1232 at ¶¶ 1, 110. They also hired Dr. Steven Borkan as an expert witness to testify that both GranuFlo® and

NaturaLyte® result in "excess bicarbonate delivery" that increases dialysis patients' risks of cardiopulmonary arrest, myocardial infarction, and ischemic stroke. SOF ¶ 19; Ex. 10, Dr. Borkan's expert report on general causation. However, as discussed below, Dr. Borkan and other experts' own testimony has shown that the NaturaLyte® claims are, in fact, unfounded.

Dr. Borkan is a professor at Boston University and also maintains an active clinical nephrology practice in facilities affiliated with DaVita. SOF ¶ 20. Despite the causation opinions he has espoused in this litigation, Dr. Borkan has previously – and repeatedly – testified under oath that a liquid acid concentrate product that delivers only 4 mEq/L of acetate to the dialysis solution is standard in dialysis practice, does not unexpectedly deliver "excess" bicarbonate to the patient, and is "acceptable." See SOF ¶¶ 21-26.

For example, in a GranuFlo®-related case pending against DaVita in federal court in Colorado (the Thornton litigation), Dr. Borkan testified in a 2014 deposition as follows:

> Q. In Paragraph 9, you have a reference to errors in the chemical composition of dialysate solution. And are the errors that you're referring to there the use of acetate in the form of sodium diacetate in the GranuFlo product or something else?
>
> A. No. I am referring to the increase in acetate caused by exposure to the GranuFlo or NaturaLyte solutions that were made with 8 milliequivalents of acetate equivalent.
>
> Q. So if there was another acid concentrate product that contained acetate in the level that converted to 4 milliequivalents of bicarbonate, would that have an error in its chemical composition, as well, or not because it's not to the level of eight that you've been talking about?
>
> A. The latter. Since it's not to the level of eight, and, therefore, would not push the patient's bicarbonate into the 40s, post dialysis. It would not result in as severe perturbations in calcium, potassium, contractility and the susceptibility to hypoxemia.
>
> * * *
>
> Q. Now, Paragraph 14 – just before Paragraph 14, there's a heading in bold that's there that says 'NaturaLyte and/or GranuFlo that contain excess acetate

increase death risk.' Do you see where I'm referring?

A. (Witness nodded.)

Q. You have to answer verbally.

A. Yes, I do.

Q. That heading, is there NaturaLyte or GranuFlo, in your opinion, that does **not** contain excess acetate, as you've described it?

A. **Yes. That would be the solutions that contain 4 mEq/L of acetate, rather than eight.**

* * *

Q. You reference in Paragraph 19 "incorrectly manufactured" NaturaLyte or GranuFlo solutions. And your reference to "incorrectly manufactured," does that mean containing a level of acetate **beyond** the 4 milliequivalents that we've talked about?

A. That's correct.

SOF ¶¶ 21-24; Ex. 12, Oct. 10, 2014 Deposition, pp. 136-137, 149, 157 (emphasis added).

Dr. Borkan testified similarly at the class certification and Daubert hearing in Thorton:

Q. Sure. I think you just said … that treating a dialysis patient with a dialysate containing acetate at a level greater than 4 milliequivalents per liter falls below the medical standard of care; is that fair?

A. That's correct.

Q. So, is it the case, then, that treating a patient with a dialysate containing acetate at a level of 4 milliequivalents or below would not fall below the standard of care?

A. In general, it turns out that that is the default or average dialysate that patients are exposed to. That's the background or baseline. And it's my understanding that there has to be some small acid component in the electrolyte solution of dialysis machines in order to maintain the proper balance of electrolytes.

* * *

Q. And the level – I think you said it a few minutes ago, and I think you said

> it yesterday – the typical amount of acetate contained in a conventional bicarbonate-based dialysate is around 4 milliequivalents?
>
> A. That's correct.
>
> Q. So that when you're talking about … excess acetate going into a patient's body and then converting into what you call excess bicarbonate, you're talking about the additional 4 milliequivalents that GranuFlo has of acetate beyond the typical other dialysate that contains lower levels?
>
> A. Yes, that's correct.

SOF ¶¶ 25-26; Ex. 13, Thornton tr. of class certification and Daubert hearing, pp. 280, 282-283.

Dr. Borkan also explained during his deposition in the DaVita litigation that he does not even see a need to advise patients at his own clinic that they are being treated with NaturaLyte®, because it contains "an amount of acetate," 4 mEq/L, "that is acceptable":

> Q. Are you aware … whether any of the patients for whom you oversee the dialysis treatment now, during the four and a half or five months that you're in clinical services, are being treated with GranuFlo or NaturaLyte?
>
> A. Yes. I am aware that my DaVita unit … uses a NaturaLyte product.
>
> Q. Okay. And have you done anything to advise your patients of that fact?
>
> A. I do not believe that advising them is necessary, **because the solutions contain an amount of acetate that is acceptable**.
>
> Q. Which is what, just so that I'm clear? Is that 4 milliequivalents or less? Is that –
>
> A. Yes. That's correct.

SOF ¶ 24; Ex. 12, Oct. 10, 2014 Deposition, pp. 161-162 (emphasis added). Dr. Borkan confirmed this testimony at the trial in the Dial case in February of this year, as discussed in Part II.C. below.

Other nephrology experts retained by Plaintiffs who are involved in treating dialysis patients likewise have testified that they utilize NaturaLyte® or other acid concentrates that, just

like NaturaLyte®, contain 4 mEq/L of acetate in treating their patients. See SOF ¶¶ 38-41; Ex. 19-22. For example, Dr. Sushrut Waikar testified in the Ogburn trial in the consolidated Massachusetts proceedings that the acid concentrate he uses for his patients at Brigham and Women's Hospital contains 4 mEq/L of acetate:

> Q. At Brigham and Women's, is the average prescription for bicarbonate 35 milliequivalents per liter?
>
> A. It is.
>
> Q. And for acetate – I'm sorry, for the acid concentrate that is used at Brigham and Women's, is there 4 acetate in it?
>
> A. There is, yes.
>
> Q. Now, do you warn your patients that there's 4 acetate in the dialysate that might metabolize into bicarbonate?
>
> A. Can you repeat? Do I warn –
>
> Q. Sure. Do you warn them? You've told us yesterday and today that acetate is bad, you don't want to expose your patients to acetate. But it sounds like you're exposing your patients to acetate, is that right?
>
> A. The answer is yes, we do use acetate in the dialysate.
>
> Q. And do you tell them that they're being exposed to acetate, the patients?
>
> A. Generally, no.

SOF ¶ 39; Ex. 20, Ogburn Trial Transcript, pp. 1018-1019.

Dr. David Goldfarb also testified at his deposition that he uses an acid concentrate which has 4 mEq/L of acetate for his patients:

> Q. At the New York Harbor clinic where you see patients on hemodialysis, you use the MinnTech Centrisol acid concentrate which has a level of 4 acetate, correct?
>
> A. That's correct.
>
> * * *

Q. Okay. The one you're using is 4 acetate, and you're using it because it's what you have, and you don't know that there's anything safer?

A. I agree.

Q. And you know NaturaLyte has 4 acetate as well, right?

A. That's right.

SOF ¶ 40; Ex. 21, June 19, 2015 Deposition of David Goldfarb, MD, pp. 161-163.

Dr. Derek Fine likewise testified that his dialysis patients are treated with NaturaLyte®:

Q. So in the inpatient unit, the acid concentrate you use is NaturaLyte?

A. Yes.

Q. And only NaturaLyte?

A. I've only seen – well, there are varying forms of it, but, yes.

Q. Okay. And in the outpatient hemodialysis clinic, the acid concentrate used is NaturaLyte?

A. Yes.

Q. And only NaturaLyte?

A. To my knowledge.

SOF ¶ 41; Ex. 22, June 3, 2015 Deposition of Derek Fine, MD, p. 136. Dr. Fine further testified that his patients, who are dialyzed with NaturaLyte®, generally "aren't alkalotic." SOF ¶ 42; Ex. 22, Fine Dep., pp. 70-71, 136, 170.

In addition, Dr. Paul Miller, the nephrologist who is responsible for instigating the labeling recall of GranuFlo® in 2012 and related litigation against FMCNA in Louisiana (SOF ¶¶ 43-44), testified as follows:

Q. So my question to you, Doctor, is, having used NaturaLyte, and you do understand that it only has 4 acetate in it, do you believe that NaturaLyte is a fine product to use, if a doctor wanted to?

A. Yes.

Q. And when you used NaturaLyte in your clinics for that period of time between the Gambro dialysate and the GranuFlo, were you able to safely and effectively use it with your patients?

A. Yes.

Q. …. When you used NaturaLyte for that period of time prior to using GranuFlo, did you believe that you were able to use NaturaLyte in a safe and effective way to care for your patients?

A. Yes.

***

Q. And do you have any criticism of a physician today who uses NaturaLyte in his or her dialysis practice?

A. No.

SOF ¶ 43; Ex. 23, June 24, 2015 Deposition of Paul E. Miller, MD, pp. 109-110, 112-113. At a subsequent deposition, Dr. Miller again confirmed that NaturaLyte® is "a fine product," contains the "standard amount" of acetate, and "is a good product to use" to treat dialysis patients. SOF ¶ 45, Ex. 24, January 19, 2016 Deposition of Paul E. Miller, MD, pp. 386-387.

C. The Dial NaturaLyte® Trial

The Court permitted the claims of the first opt-out plaintiff whose decedent was treated with NaturaLyte® (who also had been selected as an MDL bellwether case prior to the global settlement agreement) to proceed to jury trial in February of this year. At that trial, the plaintiff called Dr. Borkan as her nephrology expert on general and specific causation. Dr. Borkan acknowledged that acetic acid (which becomes acetate in the dialysate solution) is needed to prevent other electrolytes such as calcium from precipitating. SOF ¶ 30. He also admitted that NaturaLyte® has been on the market since before he became a nephrologist and has been sold with 4 mEq/L of acetate and used in dialysis treatments since the early 1980s. SOF ¶ 31. In

addition, Dr. Borkan reaffirmed his prior admissions that 4 mEq/L of acetate is an "average," "background," and "baseline" amount for an acid concentrate. SOF ¶ 32. Dr. Borkan again acknowledged that acid concentrates with 4 mEq/L of acetate, such as NaturaLyte®, do not contain "excess acetate." SOF ¶ 33. He also confirmed that he has dialyzed "many thousands" of his own patients with NaturaLyte®, is still using it today, and does not advise patients of that fact. SOF ¶ 34.

. NaturaLyte® has been used in clinical settings since the early 1980s. SOF ¶ 9. There are a variety of other acid concentrates made by other manufacturers that also contain 4 mEq/L of acetate. SOF ¶¶ 6-7 & Ex. 3-5. The plaintiff's "industry standards" expert, George Samaras, confirmed that FMCNA's disclosure of the acetate content in NaturaLyte® on the label is not any different than any other industry participant that sells a product with 4 mEq/L of acetate. SOF ¶ 7; Ex. 7, Dial Trial Tr., 8-122-123.

The jury returned a verdict for FMCNA after concluding that NaturaLyte® was not the proximate cause of the decedent's death. SOF ¶ 37; Ex. 18. The case was decided on medical causation, and the jury did not even find it necessary to reach questions regarding the adequacy of FMCNA's warnings regarding NaturaLyte®, as reflected in the verdict slip. Id.

D. Opt-Out Plaintiffs Subject to This Motion

In eight opt-out cases, available medical and product shipping records indicate that NaturaLyte® was used in the last dialysis treatment prior to injury. These cases are:

In two additional cases, the records are inconclusive as to whether GranuFlo® or NaturaLyte® was used, as both products were shipped to the relevant facility and the plaintiff has not identified the formulation that was prescribed or used for the patient at the time of his or

her last treatment. [3] These cases are:

III. LEGAL STANDARD FOR SUMMARY JUDGMENT

"Summary judgment is appropriate when 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.'" Pagano v. Frank, 983 F.2d 343, 347 (1st Cir. 1993) (quoting Fed. R. Civ. P. 56(c)). When a defendant moves for summary judgment based on a lack of evidence supporting the plaintiffs' claim, "the plaintiff must establish the existence of a triable issue which is both genuine and material to his claim." Id. Plaintiffs "must present definite, competent evidence to rebut the motion" and cannot merely rest on "conclusory allegations, improbable inferences, and unsupported speculation." Id. (quotation marks and citations omitted). If the plaintiffs' theory of liability is unsupported, summary judgment should be entered in favor of the defendant. See, e.g., Geshke v. Crocs, 740 F.3d 74, 75-77 (1st Cir. 2014); see also Koken v. Black & Veatch Constr., 426 F.3d 39, 49 (1st Cir. 2005) ("When there is so little evidence tending to show a critical element of a plaintiff's claim that the jury would have to speculate in order to return a

verdict for the plaintiff, a defendant is entitled to summary judgment.").

IV. ARGUMENT

To recover on any of their claims under any substantive law that may apply in this products liability litigation, each opt-out plaintiff must prove that the acid concentrate used in the patient's relevant dialysis treatment was the cause of the injury. See, e.g., In re Norplant Contraceptive Prods. Liab. Litig., 215 F. Supp. 2d 795, 830 (E.D. Tex. 2002) (noting "[t]he causation requirements in failure to warn claims are similar in all United States jurisdictions"); In re Mirena IUD Prods. Liab. Litig., 202 F. Supp. 3d 304, 310 (S.D.N.Y. 2016) ("As in any products liability or personal injury action, Plaintiffs must prove causation."). To prove causation in a mass tort products liability action, Plaintiffs must proffer evidence of both (1) general causation – that is, that the product is capable of causing their alleged injuries; and (2) specific causation – that the product did, in fact, cause the injury in each individual case. Id.; see also, e.g., In re Neurontin Marketing, Sales Practices, & Prods. Liab. Litig., 612 F. Supp. 2d 116, 123 (D. Mass. 2009); In re Zoloft Prods. Liab. Litig., 176 F. Supp. 3d 483, 491 (E.D. Pa. 2016); In re Breast Implant Litig., 11 F. Supp. 2d 1217, 1224 (D. Colo. 1998) (citing cases from many jurisdictions). A defendant such as FMCNA can demonstrate that there is no genuine issue of material fact as to causation by showing an absence of evidence concerning general causation. In re Norplant, 215 F. Supp. 2d at 830.

The admissions of Dr. Borkan and Plaintiffs' other experts, and the outcome in the Dial trial, demonstrate that general causation is non-existent in any NaturaLyte® case. Summary judgment should be entered in favor of FMCNA to clear the docket of these baseless claims.

A. The Allegation that NaturaLyte® Caused Any Opt-Out Patient to Experience Cardiac Arrest Is Irreconcilable with Dr. Borkan's Testimony and Other Evidence.

Dr. Borkan is Plaintiffs' expert on NaturaLyte®. While he endorses Plaintiffs'

allegations that NaturaLyte® is dangerous and defective based on the fact that it contains 4 mEq/L of acetate, his own testimony and practices demonstrate that this theory is unfounded. As detailed above, Dr. Borkan has admitted that acid concentrate products containing 4 mEq/L of acetate are "conventional," "default," and "acceptable." Further, Dr. Borkan utilizes NaturaLyte® in treating all of his own chronic hemodialysis patients.

His attempt to put a new slant on his opinions to suit Plaintiffs' litigation purposes by refusing to concede that NaturaLyte® is safe does not change the admissions he made in the Thornton case in 2014-2015 and reaffirmed during the Dial trial just six months ago. Dr. Borkan's acknowledgement that acid concentrates containing 4 mEq/L of acetate are standard in the industry and his practice of using NaturaLyte® in treating his own patients demonstrate that Plaintiffs' theory of liability lumping the NaturaLyte® and GranuFlo® products together was and is fatally flawed.

In addition to Dr. Borkan, other Plaintiffs' experts who practice clinical nephrology also have admitted that they use NaturaLyte®, or other acid concentrates that contain 4 mEq/L of acetate, in treating their dialysis patients. For example, in testifying at trial in Ogburn, Dr. Waikar, the Director of Ambulatory Services in the Renal Division at Brigham and Women's Hospital, testified that the acid concentrate used at his hospital contains 4 mEq/L of acetate, and he does not warn his patients of that fact. SOF ¶ 39. Further, Plaintiffs' expert Dr. Goldfarb testified at his deposition that his chronic hemodialysis patients are treated with a MinnTech acid concentrate called Centrisol, which contains 4 mEq/L of acetate. SOF ¶ 40. And Dr. Fine, another nephrology expert retained by Plaintiffs, testified that his inpatient dialysis patients and chronic dialysis patients are treated with NaturaLyte®. SOF ¶ 41. Significantly, Dr. Fine also

testified that these NaturaLyte® patients are not alkalotic, meaning they do not experience the type of elevated serum bicarbonate levels that Plaintiffs claim lead to cardiac arrest. SOF ¶ 42.

Over 30 years of custom and practice in the dialysis products industry also confirm that Plaintiffs' and Dr. Borkan's theory that NaturaLyte® has caused any injury are baseless. Four milliequivalents per liter of acetate has been the standard for liquid acid concentrate products since the earliest days of bicarbonate dialysis. NaturaLyte® with 4 mEq/L of acetate was cleared for sale by FDA in 1981. SOF ¶¶ 1, 3; Ex. 1. Even then, it was not a new formulation. The 510(k) application (filed by National Medical Care, the developer of NaturaLyte®) rested on "substantial equivalence" to another 4 mEq/L liquid acid concentrate product, made by Renal Systems, Inc., that had previously been cleared for sale by FDA. Id.

It has been used safely and effectively in hundreds of millions of dialysis treatments. SOF ¶ 9.

Over the next thirty-plus years, other manufacturers of acid concentrates for hemodialysis have offered liquid products with 4 mEq/L of acetate. That remains true to this day. In addition to FMCNA, the other manufacturers of hemodialysis acid concentrates all currently make and sell a 4 mEq/L liquid acid concentrate product – for example, Rockwell Medical sells its RenalPure® product in a 4 mEq/L formulation; Medivators sells its Renasol® product in a 4 mEq/L formulation; and Diasol sells its product in a 4 mEq/L formulation. SOF ¶ 6; Ex. 3. Like NaturaLyte®, these products have been on the market for decades. Plaintiffs' industry standards expert concedes that their labels all disclose the acetate contents in exactly the same way. SOF ¶ 7; Ex. 7, Dial Trial Tr. 8-122-123.

None of these manufacturers of acid concentrates with 4 mEq/L of acetate has reported to FDA (as they are required to do) any incidents, or even reports of, patient harm resulting from the

use of these products.

Even Dr. Paul Miller, the Louisiana nephrologist with a litany of complaints against FMCNA who "leaked" the Hakim Memo to FDA as referenced in Plaintiffs' complaint, acknowledges that NaturaLyte® is safe. SOF ¶¶ 43-45. In sum, to accept Dr. Borkan's stated opinion that 4 mEq/L acid concentrates can harm patients, one would have to find the entire dialysate-manufacturing industry has been producing defective products and almost every hemodialysis treatment has been dangerous. Juries should not be required to engage in such speculation. See Koken, 426 F.3d at 49. This is particularly true where Plaintiffs have no evidence to the contrary.

The Handbook Of Dialysis, a leading reference text used by practicing nephrologists and medical school nephrology professors, is in accord with Dr. Borkan's admissions in Thornton and Dial, rather than his written expert opinions tailored to Plaintiffs' shifting litigation theories. As early as the Third Edition – published in 2001 – the authors advised that:

> To circumvent the problem of calcium and magnesium precipitation, a bicarbonate-based dialysate generating system utilizes two concentrate components, a 'bicarbonate' component and an 'acid' component, the latter containing a small amount of lactic, acetic or citric acid plus sodium, chloride, potassium (if needed), dextrose (optional), and all of the calcium and magnesium. Specially designed dialysis machines mix the two components simultaneously with purified water to make the product dialysis solution. During mixing, the small amount (***usually 4 mM***) of organic acid in the 'acid' component reacts with an equimolar amount of bicarbonate in the 'bicarbonate' component to generate carbon dioxide. The carbon dioxide which is generated forms carbonic acid, which lowers the pH of the final bicarbonate-containing solution to approximately 7.0 – 7.4.

SOF ¶ 47; Ex. 27, Daugirdas, Handbook Of Dialysis, (3d ed. 2001) at p. 59-60 (emphasis added).

Notably, Plaintiffs' original Master Complaint pled that liquid acid concentrates

containing acetic acid – the category of products that includes NaturaLyte® – were "traditional." Master Complaint ¶ 97 (Doc. 467-1). Plaintiffs repeatedly and expressly distinguished between sodium diacetate, which GranuFlo® contains, from the acetic acid contained in liquid acid concentrates such as NaturaLyte®, in their effort to underscore the alleged dangers of GranuFlo®. See, e.g., Id. at ¶¶ 107, 110, 137-140. Although Plaintiffs subsequently amended their pleading, these factual assertions "still remain[] as … statement[s] once seriously made by an authorized agent, and as such [are] competent evidence of the facts stated …." Global ePoint v. GTECH Corp., 58 F. Supp. 3d 178, 190 (D.R.I. 2014) ("statements made in the superseded complaint may be party admissions, usable as such, despite subsequent amendment of the complaint," particularly when the plaintiffs' "theory of the case changes in its amendment") (citations and quotation marks omitted).

B. The Dial Trial Illustrates that NaturaLyte® Cases Are Categorically Unfounded.

A NaturaLyte® case was exhaustively presented to a jury in a month-long trial before this Court in February 2017 in the Dial matter.

As her nephrology expert, the plaintiff called Dr. Borkan, who was forced to reaffirm his prior testimony that he treats his own patients with NaturaLyte® and has done so many thousands of times, and the 4 mEq/L of acetate in NaturaLyte® is acceptable. SOF ¶¶ 30-34; Ex. 15. FMCNA presented additional evidence that NaturaLyte® has been an industry-standard product in dialysis for more than three decades, as discussed above. SOF ¶¶ 8-9.

After a short period of deliberations, the jury returned a defense verdict concluding NaturaLyte® did not cause Mr. Dial's death. SOF ¶ 37; Ex. 18.

If any opt-out case involving a patient who was dialyzed with NaturaLyte® were to proceed to trial, FMCNA expects the result would be the same. Plaintiffs' NaturaLyte® expert would be forced to acknowledge the same admissions,

Further, just as Dr. Fine testified that his NaturaLyte® patients have not become alkalotic, there is no evidence that Plaintiffs' theory of causation – acetate leading to elevated serum bicarbonate, triggering alkalosis and cardiac arrest – materialized in these cases.

[4]

And in no case is there <u>any</u> evidence that the alleged injury is attributable to NaturaLyte®, rather than other, non-dialysis-related causes, such as the patients' comorbidities.

V. CONCLUSION

In sum, Plaintiffs have not adduced any competent evidence to support their speculation that NaturaLyte® caused any injury in any opt-out case. On the contrary, NaturaLyte® is an industry standard product. Plaintiffs' original complaint acknowledged it as "traditional." The expert they later recruited in an attempt to portray it as defective, Dr. Borkan, also has conceded

[4] FMCNA contends the lack of evidence of an elevated serum bicarbonate level is an additional, independent ground for summary judgment and intends to file a separate summary judgment motion directed to these opt-out plaintiffs and others whose pre-dialysis serum bicarbonate levels were below 28 mEq/L.

it is "acceptable" – he even uses it with all his own chronic hemodialysis patients. And a jury has already considered this evidence in the context of another patient who was dialyzed with NaturaLyte® and easily concluded the product did not cause his death.

Because the record is devoid of evidence that NaturaLyte® caused any opt-out patient's alleged injuries, FMCNA is entitled to summary judgment in any cases where NaturaLyte® was used in the patients' relevant dialysis treatments. In addition, summary judgment should be entered in favor of FMCNA in opt-out cases where Plaintiffs lack evidence that the acid concentrate used was GranuFlo®, rather than NaturaLyte®.

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Respectfully submitted,

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CERTIFICATION OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served on Plaintiffs' counsel by e-mail on August 23, 2017, to:

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